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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/940,673	08/27/2001	David H. Gorski	22311/04015	5565
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24024 7590 04/10/2003

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CLEVELAND, OH 44114

EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/10/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,673

Applicant(s)

GORSKI ET AL.

Examiner

Richard G Hutson

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1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,13,18,23,28 and 33-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1,5,13,18,23,28 and 33-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

The art unit location of your application and examiner has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1652, Examiner Richard Hutson Ph.D.

Application Status

Applicants addition of new claims 41-47, Paper No. 10, 3/3/2003, is acknowledged. Claims 1, 5, 13, 18, 23, 28, 33-40 and 41-47 are pending in the instant application.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1, 13, 18, 23, 33-35, 37, 38, and 40, drawn to DNA encoding a Gax protein related to SEQ ID NO:4 (human sequence), classified in class 536, subclass 23.5.
- II. Claims 5, 33, and 38-39, drawn to DNA encoding a Gax protein related to SEQ ID NO:2 (rat sequence), classified in class 536, subclass 23.5.
- III. Claim 28, drawn to methods for inhibiting eukaryotic cell proliferation, classified in class 514, subclass 44.
- IV. Claim 36, drawn to methods for preparing nucleic acid molecules, classified in class 435, subclass 6.
- V. Claims 41, 42, 44, 46 and 47, drawn to a mammalian Gax protein related to SEQ ID NO: 4, classified in class 530, subclass 350.

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VI. Claims 41, 43 and 47, drawn to a mammalian Gax protein related to SEQ ID NO: 2, classified in class 530, 350.

It is noted that many claims (i.e. 33, 38, 41 and 47) are grouped in more than one group. These claims will be examined to the extent that they read on the elected group.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, V and VI are structurally unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the mammalian Gax proteins of Groups V and VI, and the DNAs encoding the mammalian Gax proteins of Group I and II each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The proteins of Groups V and VI are comprised of different amino acid sequences and the DNAs of Group I and II are comprised of different nucleic acid sequences. The DNAs has other utility besides encoding protein such as a hybridization probe, and the proteins can be made synthetically. Additionally, the protein can be used to perform specific biological function(s) which are independent of the function(s) of the DNA molecule.

While some of these groups are classified identically, these Groups are distinct, each from the other, by virtue of their distinct structures. Each SEQ ID NO has a different structure that is unrelated, except via the function of the encoded protein, to the

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other. No consensus sequence describing the Group is disclosed or claimed.

Moreover, these encoded proteins from different sources are only described in the instant specification using their structures; in other words, there is no description of Gax proteins from mammals having particular characteristics in common, such as pI, catalytic activity values, etc. Thus, each of these encoded proteins, as defined by their structures, is patentably distinct from the others. Moreover, a search of the two Groups would be undue considering not only the entirely distinct structure search that would not overlap whatsoever, but also the entirely distinct textual search in the non-patent literature which search would include the encoded protein name and/or activity and the source. Thus, Groups I, II, V and VI are patentably distinct, each from the other.

Groups I and II are related as product and process of use to Group III. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, a particular subgenus of methods use nucleic acid sequences encoding Gax proteins as found in Groups I and II. For this subgenus, the nucleic acid products can be used in a materially different process of using the product, such as in the recombinant production of Gax protein. Thus, Groups I and II are patentably distinct from Group III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related as product and process of use to Group IV. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acid sequence can be used for a materially different process of using that product, such as in the recombinant production of the encoded Gax protein. Thus, Groups I and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups II and IV are related by virtue of the fact that the methods of Group IV use nucleic acids encoding human Gax proteins while Group II is drawn to nucleic acids encoding rat Gax proteins. These Groups are distinct for the reasons set forth above concerning Groups I and II.

Groups III and IV are related by virtue of using nucleic acids encoding human Gax proteins in the method steps. However, these methods are distinct because the methods steps are wholly distinct in nature and they produce wholly different products. Thus, Groups III and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The proteins of Groups V and VI are unrelated to the methods of Groups III and IV as they are neither used nor made by the method of Groups III and IV.

Because these inventions are distinct for the reasons given above and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a long horizontal flourish extending to the right.

Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
April 7, 2003